

**Amendments to the Drawings:**

The attached sheets of formal drawings include minor changes to Figs 1, 2, 5C and 6. No changes are made to Figs. 3, 4, 5A and 5B. Fig. 1 adds "(T2)" next to element No. 24. Replacement Fig. 2 has changed hatch patterns reflecting non-metal material. Replacement Fig. 5C has been clarified in accordance with the specification. Replacement Fig. 6 removes needless lines at dialyzer 62. The replacement sheets replace the original sheets including Figures 1 to 6.

Attachment: Replacement Sheets

## REMARKS

This Amendment is in response to the non-final Office Action mailed December 7, 2004. Claims 1 to 52 were pending previously in the application. Of those claims, Claims 8 to 12, 14 to 17, 23 to 26 and 37 to 52 have withdrawn from consideration. The specification has been amended slightly. Figures 1, 2, 5C and 6 have been amended slightly. The amendments are highlighted on page 13 of this Amendment. Claims 1, 2, 6, 18, 20 to 22, 27, 30, 31 and 33 to 34 have been amended herein. New Claims 53 to 55 have been added. No new matter has been introduced by way of any of the amendments or additions. Please charge Deposit Account No. 02-1818 for the additional claims and any fees deemed owed.

In the Office Action, the election/restriction was made final. Claims 20 to 22 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Claims 1 to 3, 7, 13, 18, 19, 20, 21, 22, 27, 28, and 29 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,875,282 to Jordon et al. (“*Jordan*”) or by U.S. Patent No. 3,475,590 to Pins (“*Pins*”). Claims 1 to 3, 5 to 7, 13, 18, 19 and 27 to 36 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,271,086 Kamiyama et al. (“*Kamiyama*”). Claim 4 was rejected under 35 U.S.C. § 103(a) as being obvious in view of *Jordan* or *Pins* in further view of U.S. Patent No. 6,261,261 to Gordon (“*Gordon*”).

Regarding the finality of the restriction/election, Applicants remind the Patent Office of the statement at page 4 of the restriction/election requirement of July 9, 2004. At page 4 that paper states that upon the allowance of a generic claim, Applicants will be entitled to consideration of claims to additional species, which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. The provision does not require Applicants to name the claims that are generic in the response to the restriction/election requirement. Applicants therefore reserve the right to identify generic claims and to have claims meeting the requirement under the rule considered at a later date pursuant to 37 C.F.R. § 1.141.

Regarding the § 112 rejection of Claims 20 to 22, those claims have been amended. As presently presented, those claims are definite under 35 U.S.C. § 112, second paragraph. Applicants respectfully submit that the amendments to Claims 20 to 22 are non-narrowing and disclaim no subject matter with respect to the art of record.

Regarding the rejection of independent Claims 1, 13, 18 and 27 in view of *Jordan*, *Pins* or *Kamiyama*, Applicants respectfully submit that the claims as presently presented are patentably distinguished over those references. Claim 1 for example among other elements specifies a controller that causes one of the infrared heater and a second heater to be powered at a first time and both the infrared heater and the second heater to be power at a second time to maintain a desired temperature of the fluid. Support for this feature can be found for example at page 11 line 8 and page 13, line 17 of the specification.

Neither *Jordan* nor *Pins* specifies such heater control. For example, *Jordan* at column 5, line 5 states that energy transferred is accomplished by conduction, convection and radiation from heater plates, on both sides, to the disposal bag. [Emphasis added]. This statement suggests that *Jordan* cannot supply power at a first time from one of the heater plates and at a second time from both of the heater plates. Likewise, Fig. 5 of *Pins* shows an electrical diagram and illustrates heaters 16 and 18 placed in parallel with respect to each other. The circuit does not appear to provide for the ability to power only one heater at a first time and to power both heaters at a second time.

Regarding *Kamiyama*, that reference appears to disclose, teach or suggest only a single heater, namely, tubular ceramic heater 4. That singular heater heats a first quartz glass tube 5, a second quartz glass tube 6 and a third quartz glass tube 7. While *Kamiyama* teaches multiple quartz glass tubes, *Kamiyama* only appears to teach a single heater. Accordingly, *Kamiyama* does not teach or suggest a radiant heater and a secondary heater as called for in Claim 1. Moreover, *Kamiyama* does not disclose, teach or suggest a controller that causes one of the infrared heater and a secondary heater to be powered at a first time and both the infrared heater and the secondary heater to be powered at a second time to maintain a desired temperature of the fluid as set forth in Claim 1.

Applicants submit that *Jordan*, *Pins* and *Kamiyama* alone or in combination do not disclose, teach or suggest the features of presently presented Claim 1. Accordingly, those references do not disclose, teach or suggest the features of dependent Claims 2 to 7.

The patentability of Claim 1 renders moot the obviousness rejection of Claim 4 in view of *Jordan*, *Pins* and *Gordon*.

Dependent Claim 6 provides additional patentable subject matter over *Jordan*, *Pins* and *Kamiyama*. As discussed above, *Kamiyama* discloses only a single heater. *Jordan* and *Pins* both illustrate their respective dual heaters in a parallel relationship on two sides of the fluid to be warmed. Accordingly, none of those references teaches or suggests placing the secondary heater fluidly upstream of the infrared heater or fluidly downstream of the infrared heater as spelled out in Claim 6. Support for the structure of Claim 6 can be found for example at page 12, line 29. Claim 6 is therefore patentable independently over those references. Claim 53 that depends from Claim 5 also recites independently patentable structure.

Regarding independent Claim 13, Applicants respectfully submit that *Gordon*, *Pins* and *Kamiyama* do not alone or in combination disclose, teach or suggest that claim. As discussed above, *Kamiyama* discloses only a single heater 4 and therefore cannot teach Claim 13, which includes an infrared emitter and a plate heater.

Claim 13 specifies a device for inline heating that includes an infrared emitter and a plate heater. Neither *Pins* nor *Gordon* disclose an infrared emitter. Both references disclose the provision of electrical resistance heaters and do not disclose, teach or suggest the inclusion of an infrared emitter. Indeed, those references only mention radiant energy in passing. *Jordan* at column 5, line 5 mentions that energy transfer is accomplished by conduction, convection and radiation from heater plates. The heater plates 92 of *Jordan* are taught to include silicone rubber and to be vulcanized to the energy reservoirs 88 and 90 (*Jordan* at column 7, line 23). *Jordan* does not disclose, teach or suggest the inclusion of an infrared emitter. Likewise, *Pins* briefly mentions at column 5, line 18 that there is some heating by radiant heat from the sidewalls of block 11. Heaters 16 and 18 of *Pins* however are clearly taught to be electrical heaters (*Pins* at column 4, line 70), not infrared emitters. Accordingly, none of the references teaches a combination infrared emitter and a plate heater for in-line heating of a fluid through a disposable dialysis unit. Claim 54 that depends from Claim 13 is also independently patentable. Support for new Claim 54 is found for example at page 16, line 7 of the specification.

Referring now to Claim 18, none of the cited references including *Jordan*, *Pins* and *Kamiyama* discloses the claim as presently presented. Claim 18 specifies multiple heaters. As discussed above, *Kamiyama* discloses only a single heater. Claim 18 also specifies a radiant energy heater having a radiant energy emitting bulb and an apparatus that aids in directing

radiant energy in a direction towards a first section of a fluid container. None of the references discloses a radiant energy heater having a radiant energy emitting bulb. Claim 18 and its dependants are respectfully submitted therefore to be patentable at this time.

Various claims depending from Claim 18 also recite patentable subject matter. For example, none of the references discloses the apparatus of dependent Claim 20, which describes features of the fluid container. Still further, none of the references describes, teaches or suggests the features of Claim 21, which also involves the fluid container. Further still, dependent Claim 22 discusses a preheating and final heating configuration, which does not appear to be disclosed by the cited references. Further, added Claim 55 that depends from Claim 18 specifies further characteristics of the bulb, which are not disclosed, taught or suggested by any of *Jordan*, *Pins* or *Kamiyama*. Support for new Claim 55 is found for example at page 13, line 22 of the specification.

Regarding Claim 27, the claim as presently presented specifies a second heater of a different type than the radiant heater, which heats at least a portion of the dialysis fluid traveling along the fluid flow path. As discussed above, *Kamiyama* only discloses one heater. While *Jordan* and *Pins* each disclose parallel heaters, the heaters are disclosed in each case to be of the same type. In particular, the heating pads 92 of *Jordan* are each specified to include silicone rubber and to be vulcanized to energy reservoirs 88 and 90 (*Jordan*, column 7, line 23). The heaters 16 and 18 of *Pins* are both disclosed to be electrical heaters. In both references, the two heaters are the same, teaching away from Claim 27. Claim 27 specifies that the second heater is of a different type than the radiant heater. Accordingly, Applicants respectfully submit that Claim 27 and Claims 28 and 29 that depend from Claim 27 are each in condition for allowance at this time.

Regarding Claim 30, Applicants respectfully submit that the art of record does not teach or suggest that claim. Claim 30 specifies multiple heaters as discussed above, *Kamiyama* discloses only one heater. Claim 30 also specifies a temperature sensor coupled operably to a controller and having a signal indicative of a temperature of a dialysis fluid, wherein the controller is operable with a temperature sensor to cause power to one of the radiant energy heater or the second heater to be varied as needed. *Pins* and *Jordan* alone or in combination do not appear to disclose Claim 30 as presently presented. *Pins* discloses a thermostat control,

wherein a control thermostat 31 is opened when end anchors 38 and 39 move away from each other. The separation of end anchors 38 and 39 causes an actuating member to flatten and ultimately pull a contact 36 away from engagement contact 37 (*Pins*, column 4, lines 29 to 35). A second thermostat 41 is a safety thermostat (*Pins*, column 5, lines 38). Notably, there does not appear to be any suggestion in *Pins* of varying power to the heaters 16 and 18.

*Jordan* at column 8, line 12 appears to teach an adjustment of power to the energy reservoir. There is no disclosure or suggestion however that power to only one reservoir is varied. That is, heater elements 92 appear to be controlled the same, and there is no disclosure that power to only one reservoir is varied. *Jordan* does not disclose, teach or suggest independent power control for only one heater at a particular time. Applicants accordingly respectfully submit that Claim 30 and Claims 31 to 36 depending from Claim 30 are patentably distinct over *Pins*, *Jordan* and *Kamiyama*. Applicants also respectfully submit that *Pins*, *Jordan* and *Kamiyama* do not teach or suggest various ones of the dependent Claims 31 to 36. The Office Action does not show where the apparatuses of Claims 31 to 36 are found in *Pins*, *Jordan* and *Kamiyama*.

Various claim amendments have been made for clarification or to better define the scope and breadth of the present invention. These amendments are non-narrowing, have been made for no statutory reason and disclaim no subject matter on the art of record. These amendments include amendments to Claims 2, 6, 31, 33 and 34.

For the foregoing reasons, Applicants respectfully submit that the above-identified patent application is now in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

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Dated: 3/7/05